Recent US nationwide research on malpractice lawsuits shows that the most common cause of medical malpractice suits against radiologists was error in diagnosis (mainly failure to diagnose instead of delay); the category next in frequency was procedural complications, followed by inadequate communication with either patient or referring physician. Risk management is a fundamental instrument to prevent and limit errors and adverse events.

This article analyzes risk management in radiology addressing the most common ethical-legal issues on appropriateness of prescriptions, informed consent, and management of adverse events.

Effective remedial actions are proposed to avoid malpractice claims that would help physicians in preventing malpractice stress syndrome, leading to defensive medicine.

Risk management is generally defined as the identification, assessment, and prioritization of risks (defined in ISO 31000 as the effect of uncertainty on objectives, whether positive or negative) followed by coordinated and economical application of resources to minimize, monitor, and control the probability and/or impact of unfortunate events. In healthcare, risk management is defined as the “clinical and administrative activities undertaken to identify, evaluate, and reduce the risk of injury to patients, staff, and visitors and the risk of loss to the organization itself.”

Risk management may be either proactive (avoiding/preventing risk) or reactive (minimizing loss or damage after an adverse/bad event). In 1990, British psychologist James Reason introduced risk analysis and management systems to human error. The preferred approach to risk and error analysis should be “the system approach” which acknowledges that humans make mistakes and errors are to be expected, but views these as a consequence and instead focuses on identification of an underlying system failure.

Detection and analysis of risk and prevention of errors may be built on a series of safeguards (physical, electronic, personal, procedural, and administrative). In the field of radiology, regular workflow may be impaired either by latent factors (ie, equipment design, materials such as contrast agents, devices; protocols, policies, rules, and regulations; and routine maintenance of all systems involved) or active failure (human errors) which include procedural complications (failure to execute a procedure) or mistakes and diagnostic misses and misinterpretations.

The fundamental issue of risk and error management is to develop processes and safeguards aimed at reducing or preventing the occurrence of errors and minimizing the degree of harm. Such behavior should reduce the risk of harm to the patient and, thereby, malpractice litigation. Creating standard protocols and rules should prevent and minimize this; however, it’s obvious in theory but not necessarily in clinical daily practice where those concepts have to be applied.

In this review, the following main safeguards are described that can be applied in the radiology setting:

- Appropriateness and Standard of Care
- Informed consent and appropriate documentation
- Management of adverse events

**Appropriateness and Standard of Care**

Appropriateness is defined as the ability to make the most logical imaging or treatment decision for a specific clinical condition. The choice of a radiology request is made based on evidence...
Based criteria and conditioned by previous radiological procedures on their specificity and appropriateness, by the evaluated diagnostic outcomes, and by the economic impact of inappropriate examinations. One study analyzed 4,018 outpatient requests assessing a 56% rate of appropriate requests and demonstrating that appropriate prescriptions provided with a specific clinical question led to significantly higher confirmation rates of the diagnostic hypothesis.

To increase appropriateness, practitioners should work collaboratively with colleagues, respecting their skills and contributions, being aware of how behavior may influence others within and outside the team. A reduction in inappropriate requests may be primarily obtained by the development of guidelines that define common behaviors and skills leading to a standard of care. These are not intended to be legal standards of care, but recommended conduct in specific areas of clinical practice that may be modified as determined by individual circumstances and available resources. Several international radiology societies, such as the American College of Radiology (ACR), European Society of Radiology (ESR), Radiological Society of North America (RSNA), Cardiovascular and Interventional Radiological Society of Europe (CIRSE), and Society of Interventional Radiology (SIR) endorse guidelines for any kind of radiological exam or interventional procedure.

The ACR Appropriateness Criteria represents the most comprehensive evidence based guidelines for diagnostic imaging selection and radiotherapy protocols. Also, both SIR and CIRSE have developed several practice guidelines to improve the standard of quality of numerous image guided interventional procedures. The CIRSE checklist is a straightforward manner to avoid errors after the procedure and in the management and follow-up care of the patient. A checklist should be applied in each situation to regulate any kind of workflow, eg, attaching signs on the wall of each working area (ie, CT, MR, and interventional suite). A useful workflow checklist for radiological exams/procedures is shown in Table 1.

Web-based computerized physician order entry (CPOE) systems, due to the

<table>
<thead>
<tr>
<th>TABLE 1. Patient Workflow Checklist</th>
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<tbody>
<tr>
<td>Radiologic exam/procedure planning</td>
</tr>
<tr>
<td>Discussed indication with referring physician/fasting order given</td>
</tr>
<tr>
<td>Relevant clinical history</td>
</tr>
<tr>
<td>Previous imaging exams visualized</td>
</tr>
<tr>
<td>Informed consent obtained</td>
</tr>
<tr>
<td>Check pertinent laboratory tests</td>
</tr>
<tr>
<td>Assess potential adverse events to contrast media (if any risk is present, a prevention therapy must be planned)</td>
</tr>
<tr>
<td>Seeking for some drug to suspend/administer before the exam/procedure (ie, anticoagulants, beta-blockers)</td>
</tr>
<tr>
<td>Check if anesthesiologist or bed in ICU is necessary</td>
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</tbody>
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Source: This table has been modified and adapted from CIRSE IR Patient Safety Checklist available at http://www.cirse.org/index.php?pid=412.
electronic entry of data, may decrease delay in order completion, can reduce errors related to handwriting or transcription, allow order entry at the local point of care or off-site, provide error checking for duplicate or incorrect doses or tests, and simplify inventory and posting of charges. In radiology, immediate visualization of clinician requests, laboratory tests, images, and reports of exams are fundamental to reduce communication errors and to avoid delay of patient workflow in particular when an emergency occurs. Moreover, practice guidelines and workflow lists may be posted online and immediately shared across referring physicians and radiologists, thus creating electronic standard protocols and procedures.

One study found that overutilization in imaging exams is related to lack of knowledge of appropriateness criteria and can often lead to defensive medicine.9 The radiologist should challenge sub-optimal, inadequate or limited imaging examinations or include in radiology reports statements that describe limitations of an examination when present (ie, study should be repeated when patient’s clinical condition permits).10 A correct, formal report requires fundamental competencies, such as proper knowledge, skills, and behavior.11 Apart from the structure of the report, proof-reading to avoid vague language or voice recognition errors that may lead to malpractice litigation is important.

Informed Consent and Appropriate Documentation

Informed consent represents a contract of duty of care between the patient and the radiologist. According to the 1997 International Convention on Human Rights and Biomedicine: "An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time."12 Important articles regarding patients who cannot give their consent are the following13:

-- Article 6.2. Where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorization of his or her representative or an authority or a person or body provided for by law.

-- Article 6.3. Where, according to law, an adult does not have the capacity to consent to an intervention because of a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorization of his or her representative or an authority or a person or body provided for by law. The individual concerned shall as far as possible take part in the authorization procedure.

-- Article 8: Emergency Situation. When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned. Those and the rest of international rules have been turned in proper state laws across different Countries for example, RCR endorsed a standard of practice document to provide guidance to radiologists involved in obtaining the informed consent.

Legal requirements of an informed consent may vary from state to state; however, it is generally considered good practice to ensure that consent is given in the appropriate environment, in the proper manner, and in the presence of appropriate and relevant information.13 To avoid malpractice, the facility must be sure of the following:

• The patient has the right information to make a decision.
• The information has been presented in a way/language that the patient can understand.
• The patient has shared and is convinced of the process of the radiologic exam and agrees with its outcome.

Informed consent should be obtained for invasive diagnostic or therapeutic procedures. Physicians provide patients or their legal representatives information about the purpose and nature of the diagnostic procedure, risks, complications, and expected benefits. Procedures associated with higher levels of radiation require assessment of the radiation dose that should be noted in the patient’s medical record. Complete information also includes explanation of any reasonable alternatives to the procedure or treatment or of the risk of not accepting the procedure or treatment.

The informed consent should be executed and appropriately documented, which is most commonly done by having the patient sign a consent form. The physician’s name must appear on the consent form prior to the signature by the patient. A copy of the consent form should be placed in the medical record. During an emergency, if an informed consent cannot be obtained from the patient or from his or her legally authorized representative, the physician treating the patient should determine the immediacy of the need for the diagnostic exam or interventional procedure.12,13 One study reported a high number of patients not adequately prepared for examinations due to incomplete clinical information or incomplete consent forms.14 Patient preparation is fundamental in guaranteeing a safe radiologic exam.
Management of Adverse Events

An analysis of Joint Commission sentinel event data (reported from 1995 to 2002) related to wrong-site surgeries (n = 209) showed that these adverse events can be classified in the following principal groups15:

- Communication: including communication with the patient and among members of the surgical team; availability of information; and operating room hierarchy;
- Patient management: such as preoperative assessment of the patient; and
- Clinical performance: orientation and training, the procedures used to verify the operative site, and distraction.

Errors in radiology practice are quite common, amounting to about 4% of radiologic interpretations rendered by radiologists.16 A recent review outlined that both in US and in European countries the most common error is failure to diagnose, particularly in breast and skeletal radiology.17 Complications related to interventional procedures represent the second most frequent cause of claims made.

One study analyzed 3976 incidents in the Australian Radiology Events Register and reported that, most frequently, there is an incident due to incorrect information on the request form (52% of cases), followed by delayed communication of a diagnosis (36%), or communication of a wrong diagnosis (36%). Also, errors are relatively common during patient preparation (34%), when requesting imaging (27%), and when communicating a diagnosis (23%).18

Finally, adverse events related to contrast media are relatively rare; however, in some cases they are life-threatening events. The incidence of acute adverse reactions to contrast agents is approximately 2–3% with iodinated low-osmolarity contrast agents and lower for gadolinium based contrast media, accounting for 0.079% of cases.19,20 The ACR recently developed the “Manual on Contrast Media v8” where a selection of patients, prevention, and treatment of any kind of adverse reaction to contrast media are described.21 They classified adverse reaction as: mild, moderate, and severe. History of immediate adverse reaction to contrast agents is the most significant risk factor. A previous allergy mediated disease (eg, asthma, atopic dermatitis, and in particular urticaria and history of previous allergy to drugs other than contrast agents) is also considered significant risk factor.

Other predictors of an allergy are: iodinated contrast agent concentration >70%, age <50 years old, and a total contrast agent dose >65 g.19,21 An allergy to gadolinium based contrast media seems to be significantly more frequent in females, in those who had prior allergic events to gadolinium or other, and in MR exam of abdomen.20 Findings suggest that education for contrast reaction management needs be updated through annual lectures and simulation training. It may be also worthwhile testing knowledge or skills.22

In evaluating a patient for a potential contrast reaction, five important immediate assessments should be made23:

- How does the patient look?
- Can the patient speak? How does the patient’s voice sound?
- How is the patient’s breathing?
- What is the patient’s pulse strength and rate?
- What is the patient’s blood pressure?

Another matter is the relationship between contrast media and chronic kidney disease. Gadolinium containing contrast is now considered contraindicated in patients with GFR < 60 mL/min, especially in patients with GFR < 30 mL/min due to the high risk of developing both Contrast Induced Nephropathy and Nephrogenic Systemic Fibrosis.21,24

A useful checklist should be developed and applied before any kind of diagnostic and interventional exam to prevent adverse reactions to contrast agents (Table 2). Adverse events involving medical devices that put or have the

| TABLE 2. Checklist to assess potential adverse events to contrast media administration. |
| Check point                              | Result                                           |
| Age                                     | > 50 or <50 y                                   |
| Gender                                  | M/F                                             |
| Allergic history                         | Atopic dermatitis, asthma, urticaria.           |
| Medical history/drugs                    | diabetes, hypertension, dyslipidemia; metformin. Allergy to drugs. |
| Laboratory values                        | Blood urea nitrogen, Creatinine, Total-bilirubin, AST, ALT, LDH, Glucose. HgbA1c, WBC, Hgb, Plt. |
| Total contrast agent dose                | < or > 65g (iodinated)                          |
| Contrast agent concentration            | < or > 70%. (iodinated)                         |
| Type of contrast agent                   | Gadolinium based/iodinated                      |
Risk prevention strategies may have a positive effect on safety, not only by determining changes in patient care workflows, but also by changing staff behavior and knowledge.

Potential to put the safety of a patient at risk should be reported as suspected adverse drug reactions.

Whatever adverse event occurred in a medical imaging setting, incident reporting strategies should be developed among healthcare practitioners and patients in order to reduce risk. Incident reporting strategies vary from documentary analysis to questionnaires, interviews, and patient complaints. In radiology, corrective strategies to address safety concerns related to new technologies, patient transfers, and inadequate test result notification policies seems to be relevant. Results from a recent report outlined that incident reporting strategies should be made “easy,” informal, and person-centered instead of rigid. This behavior may suggest that applying current guidelines to the local healthcare reality may result in a more practical and acceptable method for risk prevention.

One study reported standard incident reporting systems (based on voluntary reporting by the healthcare staff) could not report all incidents in hospitals so they should be combined with complementary information from patient complaints and retrospective chart review. However, risk prevention strategies may have a positive effect on safety, not only by determining changes in patient care workflows, but also by changing staff behavior and knowledge. It is paramount that incident reports should be analyzed and discussed by the whole healthcare staff. In the clinical reality, there are usually some difficulties and barriers (organizational and individual factors) in reporting incidents and also in applying the “learned lesson” from incident reports to improve patient safety. Finally, some measures to overcome such troubles have been proposed: enhancing safety culture, introducing a reward system, implementing incident reporting systems, improving staff awareness of patient safety and incident reporting and others.

Conclusion

Considering the US and European studies of malpractice in radiology, an increasing trend is notable. The risk of legal complications in Italy is progressively approaching that of the United States, where it is estimated that 40% of radiologists are taken to court, on average, once every 5 years. To guarantee a good medical practice, the entire medical team must be familiar with guidelines and developments that affect the facility, keeping up to date with laws, guidelines, and regulations in order to improve quality. Moreover, any information about patients should be clearly recorded (e.g., relevant clinical findings, decisions made and actions agreed, who made the decisions and agreed to the actions, information given to patients, any drugs prescribed or other investigation or treatment, and who is making the record and when).

A culture that allows all staff to raise concerns openly if patient safety, dignity, or comfort is or may be compromised should be promoted and encouraged. A comprehensive risk management strategy in radiology is strongly recommended in order to avoid and prevent potential errors and adverse events that may occur through the workflow. Finally, preventing errors and limiting adverse events may help prevent malpractice lawsuits.

References


Anderson JE, Kodate N, Walters N, Dodds A. Can incident reporting improve safety?
Questions

Instructions: Choose the answer that is most correct.

1. The most common cause of medical malpractice suits against radiologists was:
   a. Inadequate communication with patient or referring physician
   b. Procedural complications
   c. Prolonged wait time for appointment
   d. Error in diagnosis

2. Being “proactive” in risk management means:
   a. Minimizing loss after a bad event
   b. Minimizing damage following an adverse event
   c. Avoiding/preventing risk
   d. None of the above

3. The preferred approach to risk and error analysis should be:
   a. The system approach
   b. The identification approach
   c. The classification approach
   d. The organization approach

4. In radiology, latent factors that may impair regular workflow include all of the following EXCEPT:
   a. Protocols
   b. Equipment design
   c. Human error
   d. Routine maintenance of all systems involved

5. Appropriateness is defined as: The ability to make the most logical imaging or treatment decision for a specific clinical condition.
   a. True
   b. False

6. Which of the following is NOT an international radiology society that endorses guidelines for any kind of radiological exam or interventional procedure?
   a. American College of Radiology (ACR)
   b. United Radiology International Club (URIC)
   c. European Society of Radiology (ESR)
   d. Cardiovascular and Interventional Radiological Society of Europe (CIRSE)
7. Under the Patient Workflow Checklist (Table 1), radiologic exam/procedure planning includes:
   a. Radiologist/interventional radiology team, anesthesiologist introduced
   b. Post-procedural/exam note written
   c. Check IV access
   d. Relevant clinical history

8. What year did the International Convention on Human Rights and Biomedicine establish that informed consent represents a contract of duty of care between the patient and the radiologist?
   a. 1979
   b. 1997
   c. 1987
   d. 2007

9. The following article regarding patients who cannot give their consent addresses an emergency situation.
   a. Article 4
   b. Article 10.6
   c. Article 6.3
   d. Article 8

10. To avoid malpractice, the facility must be sure of the following:
    a. The patient has the right information to make a decision
    b. The information has been presented in a way/language most familiar with the physician
    c. The patient has paid for the procedure in full prior to dismissal
    d. All of the above

11. Physicians provide patients or their legal representatives information about:
    a. Risks
    b. Nature of the diagnostic procedure
    c. Expected benefits
    d. All of the above

12. The physician’s name must appear on the consent form prior to the patient’s signature.
    a. True
    b. False

13. Errors in radiology practice amount to what percentage of radiologic interpretations rendered by radiologists?
    a. 25%
    b. 4%
    c. 8%
    d. 16%

14. The most frequent incident according to an Australian Radiology Events Register was:
    a. Delayed communication of a diagnosis
    b. Communication of a wrong diagnosis
    c. Incorrect information on the request form
    d. Error when requesting imaging

15. A predictor of an allergy includes:
    a. <50 years old
    b. <25 years old
    c. <10 years old
    d. >75 years old

16. When evaluating a patient for a potential contrast reaction, how many important immediate assessments should be made?
    a. 10
    b. 8
    c. 5
    d. 3

17. There is a relationship between contrast media and:
    a. Liver disease
    b. Kidney disease
    c. Heart disease
    d. Hearing loss

18. Which of the following is NOT on the checklist to assess potential adverse events to contrast media administration (Table 2)?
    a. Age
    b. Gender
    c. Race
    d. Allergic history

19. Incident reporting strategies should be made:
    a. Staff-centered
    b. Clinic-centered
    c. Person-centered
    d. Formal and thorough

20. How often do 40% of radiologists in the United States get taken to court?
    a. Once every 2 years
    b. Once every 5 years
    c. Once every 10 years
    d. Once every 15 years